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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,958	11/13/2003	Eran Blaugrund	67705/JPW/GJG/JBC	9422

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,958	BLAUGRUND ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/4/2004; 9/13/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group II, claims 1-12 drawn to a method for treating amyotrophic lateral sclerosis (ALS) in a subject in need of such treatment comprising administering to the subject R (+)-N-propargyl-1-aminoindan or a pharmaceutically acceptable salt thereof in an amount effective to treat ALS in the subject, classified in class 514, subclass 647 is acknowledged. The traversal is on the ground(s) that there would not be a serious burden on the Examiner if restriction were not required because a search of the prior art relevant to the claims 13-16 i.e. Group I, would not pose a serious burden once the prior art for claims 1-12, i.e., Group II, has been identified. This is not found persuasive because the inventions of Group I and Group II are independent and distinct for the reasons given in previous Office Action as the product as claims in the Group I can be used in a materially different process of using that product because the product as claimed can be used to treat depression. It is noted that the medical disorder of depression is different from the treatment of amyotrophic lateral sclerosis. Further, the Examiner has established the reasons why there would be a serious burden on the Examiner by explaining that each of the Group I and Group II has acquired a separate status in the art because of their recognized divergent subject matter. (see page 3, restriction requirement) MPEP 808.02. Therefore, the restriction requirement made on the previous Office Action is deemed proper and made Final.

Accordingly, claims 1-12 have been examined because they are elected invention and claims 13-16 are withdrawn from consideration since they are non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Youdim et al. (WO 95/11016) in view of Kaal et al. (Journal of Neurochemistry, 2000).

Youdim et al. teach Applicant's active agent, R(+)-N-propargyl-1-aminoindan (Rasagiline) useful for the treatment of a neurodegenerative disease. (abstract). Youdim et al. teach the therapeutically effective amount of the agent is about 0.1mg to about 100mg. (page 23, lines 27-32, claim 29). These amounts encompass Applicant's amounts set forth in claims 4 and 12. Youdim et al. teach that a pharmaceutically acceptable salts of the agent include, but are not limited to, the mesylate, maleate, fumarate, tartrate, acetate, phosphate and sulfate salts. (page 21, line 34-page 22, line 4).

Youdim et al. do not teach the treatment of amyotrophic lateral sclerosis (ALS) and further comprising 2-amino-6-trifluoromethoxy benzothiazole (riluzole) and its amounts.

Kaal et al. teach that ALS is a neurodegenerative disease characterized by selective motor neuron death. (abstract). Kaal et al. teach that riluzole is a drug currently used for the treatment of amyotrophic lateral sclerosis.

It would have been obvious to one of ordinary skill in the art to employ Rasagiline for the treatment of ALS because Youdim et al. teach that Rasagiline is useful for the treatment of a neurodegenerative disease and because Kaal et al. teach that ALS is a neurodegenerative disease. One would have been motivated to employ Rasagiline for

the treatment of ALS in order to achieve an expected benefit of well-known efficacy in treating a neurodegenerative disease which includes ALS as taught by Kaal et al. There is a reasonable expectation of successfully treating ALS by employment of Rasagiline because Rasagiline is effective for the treatment of a neurodegenerative diseases which includes ALS as taught by Kaal et al.

It would have been obvious to one of ordinary skill in the art to combine riluzole in its therapeutic amounts with Rasagiline for the treatment of ALS because each of the active agent, particularly riluzole is a drug currently used for the treatment of neurodegenerative disease such as ALS, and because Rasagiline is useful for treating neurodegenerative diseases which also includes ALS. One would have been motivated to combine riluzole and Rasagiline in a single formulation for the treatment of ALS in order to achieve an expected additive effect of treating neurodegenerative diseases including ALS. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
December 18, 2006